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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/073,596 05/06/98 STEINMAN

R 20164000US5

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HM22/0327

EXAMINER

VANDER VEGT, F

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

03/27/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/073,596

Applicant(s)
Steinman et al

Examiner
F. Pierre VanderVegt

Group Art Unit
1644



☒ Responsive to communication(s) filed on Dec 22, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), ~~or thirty days, whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 82-100 ~~is~~are pending in the application.

Of the above, claim(s) 86-88, 90-93, 98, and 100 ~~is~~are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 82-85, 89, 94-97, and 99 ~~is~~are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

This application is a divisional of application S.N. 08/458,230, which is a divisional of application S.N. 08/040,677, which is a continuation-in-part of application S.N. 07/981,357, which is a continuation-in-part of application S.N. 07/861,612. Applicant should amend the priority information on page 1 of the specification to update the status of each of the priority applications, including adding the relationship of the instant application to the 08/040,677 application on the declaration, and to combine the data inserted before line 5 and the data at lines 12-15 into a single priority statement.

Claims 82-100 are currently pending in this application.

Election/Restriction

1. Applicant's election **without traverse** of Group I, claims 82-97 and 99, in paper No. 6, filed December 22, 1999, is acknowledged.

Applicant's election **without traverse** of the three-part species A) dendritic cell precursor obtained from blood, C) dendritic cell precursors pulsed with microorganism, and B) dendritic cell pulsed with mycobacteria antigen, ultimately reading upon claims 82-85, 89, 94-97 and 99, in paper No. 6, filed December 22, 1999, is acknowledged.

2. Claims 86-88, 90-93, 98 and 100 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without traverse** in Paper No. 6.

Accordingly, claims 82-85, 89, 94-97 and 99 are the subject of examination in the present Office Action.

Claim Rejections - 35 U.S.C. § 112

3. Claims 83-85, 89, 94-95 and 99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 83-85, 89, 94-95 are ambiguous and unclear in that they are drawn to "dendritic cell precursors" which have been "pulsed" with antigen. This is unclear because once the dendritic cells have been pulsed, in order to express antigenic fragments on their surface, they are no longer precursors, rather they become mature antigen presenting cells. Accordingly, because the object of the claims is still the dendritic cell precursors, the recitations of pulsing with antigen do not provide meaningful limitation to the claimed invention. Applicant should therefore amend the claims to more clearly indicate the pulsed cells as the object of the claims, if these cells are indeed the intended object of the claims.

Claim 99 is ambiguous and unclear in the recitation of milligrams of antigen per dose, as it is unclear how many pulsed cells comprise a dose. There is no relation in the claims of antigen amount to cell quantity or density of antigen density upon the surface of the cells in the composition.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 82-85, 89, 94-97 and 99 are rejected under 35 U.S.C. 102(b) as being anticipated by Knight et al (U on form PTO-892).

The Knight et al reference teaches the isolation of peripheral blood from animals which inherently contains dendritic cell precursors. Applicant is reminded that the claims recite "comprising," which is an open term inclusive of any isolated sample comprising said dendritic cell precursors. The term "isolated" merely indicates the removal of the sample comprising the dendritic cell precursors from the body and does not indicate any degree of purification. Applicant is further reminded that the dependent claims are still drawn to dendritic cell precursors and once the cells are pulsed, they become mature antigen presenting cells. The pulsing does not

modify the claimed precursors. The prior art teaching anticipates the claimed invention. Claims 95, 97 and 99 are included because human blood is a pharmaceutically acceptable carrier [96] and dendritic cells within the composition are clearly shown to be antigen-pulsed, as they are able to stimulate T cell proliferation in a mixed lymphocyte reaction (page 601 in particular) [97, 99].

Conclusion

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

6. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2000 366-day calender) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
Technology Center 1600
February 28, 2000



F. PIERRE VANDERVEGT
PATENT EXAMINER